

## II. REMARKS

Favorable reconsideration of this application in the light of the amendments and the following discussion is respectfully requested. Claims 1 and 5-9 have been amended to further clarify the claimed invention and without narrowing the scope thereof. Support for the amendments can be found, for example, at page 3 line 13 to page 4 line 2; page 34 line 21 to page 35 line 3; and page 36 lines 3-24 of the specification, and in Figures 19-21. Claims 1-19 are pending.

### **§ 112 Rejections**

Claims 1-19 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has asserted that the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

#### **A. Claims 1-9**

With regard to the casting anchor, it is noted that claim 1 requires "positioning a casting anchor within the test socket, the casting anchor being engaged with an alignment member extending out through a hole in the test socket; introducing a molding material into the test socket so as to at least partially encase the casting anchor and allowing the molding material to set to form a model; separating the test socket from the model and disengaging the casting anchor from the alignment member; (and) providing an adapter bracket having at least one through-hole adjacent the model

and introducing the alignment member through the at least one through-hole in the adapter bracket and into engagement with the casting anchor to position the adapter bracket relative to the model." The Examiner concludes that, "based on the generic terminology used (i.e., 'casting anchor'), and the limited disclosure concerning the structure and specific positioning of the casting anchor, undue experimentation would be required of one of ordinary skill in the art."

Applicant had previously selected the terminology "casting anchor" to convey that the noted structure was being as an anchor in the casting. However, in view of the Examiner's objections to this terminology, claims 1 and 5-9 have been amended to refer simply to an "anchor" rather than a "casting anchor." The term "anchor" is used interchangeably in the specification with the term "head cap 118." For example, it states at page 36 line 3 that "[t]he head cap or anchor 118 is then threaded onto the end of the alignment screw 112 until the head cap 118 is positioned about ½ inch from the bottom of the cast."

There is ample description in the specification and drawings of the head cap or anchor 118. For instance, it is suggested, at page 34 line 22 to page 35 line 3, that "[t]he cross-section of the body portion 120 of the head cap 118 is preferably formed with one or more corners and may be, for example, triangular, square, rectangular, pentagonal, hexagonal, etc. This configuration helps to prevent the head cap 118 from turning or coming out of the plaster during use." Examples of a suitable structure for the head cap or anchor 118 are illustrated in Figures 19-21. As further noted in original claim 5 and shown in these figures, the head cap or anchor 118 may include a shoulder portion to aid in preventing longitudinal movement of the anchor relative to the model.

Clearly, there is ample description in the specification and drawings of the head cap or anchor 118 to enable one skilled in the art to practice the claimed method.

According to the method of claim 1, the anchor need only be a structure that can be positioned within the test socket, engaged with an alignment member, at least partially encased by a molding material introduced into the test socket, then disengaged from the alignment member, later re-engaged with the alignment member, and then again disengaged from the alignment member.

Section 112 requires only an objective enablement; that is, the invention needs to be sufficiently disclosed through illustrative examples or terminology to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed. *In Re Marzocchi*, 169 USPQ 367 (Fed. Cir. 1971). One of ordinary skill in the art must be able to make and use the invention without "undue experimentation." Some experimentation on the part of the artisan is not fatal. *Northern Telecom, Inc. v. Data Point Corp.*, 15 USPQ 2d, 1321 (Fed. Cir. 1990). The patent document need not be a production specification, either the experimentation must be routine, or the specification must give "a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed." *PPG Industries v. Guardian Industries, Corp.*, 37 USPQ 2d 1618 (Fed. Cir. 1996).

For all of the reasons discussed above, it is respectfully submitted that the Examiner has failed to meet the initial burden to establish a reasonable basis to question the enablement provided for the invention of claims 1-9. See *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a

reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). As noted at MPEP 2164, a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Accordingly, and for all of the reasons discussed above, it is requested that the Examiner reconsider and withdraw the rejection of the claims 1-9 based upon 35 USC §112, first paragraph.

#### B. Claims 10-19

It is further noted that claim 10 requires "applying a socket forming material about at least a portion of the model and the adapter bracket." In this regard, it is asserted in the Office Action that, "based on the limited disclosure concerning the positioning of the socket forming material and a confusing illustration (the exploded perspective view of the apparatus and prosthetic device shown in Figure 20), undue experimentation would be required of one of ordinary skill in the art."

Claim 10 defines a method of forming a prosthetic residual limb test socket comprising providing an adapter bracket having an upper mounting face, a lower mounting face and a generally smooth sidewall extending therebetween, the sidewall including a plurality of bores in which a corresponding plurality of removable posts are

received, securing the adapter bracket to a model of a residual limb, and applying a socket forming material about at least a portion of the model and the adapter bracket, the socket forming material covering the plurality of removable posts but not the lower mounting face of the adapter bracket.

As noted in the specification, Fig. 20 is a somewhat schematic, exploded perspective view of the **apparatus** of Fig. 19 and prosthetic device, while Fig. 19 is noted to be an exploded perspective view of an apparatus for forming a prosthetic device with transfer of proper alignment in accordance with the invention.

Thus, Fig. 20 does not purport to be an illustration of the method of claim 10. The socket forming material is not shown in Fig. 20. Of course, drawings are generally not even required with regard to method claims. See, *In re Hacklander*, 122 USPQ 278 (Comm'r) and MPEP §608.02.

In addition, the formation of a test socket by the application of a socket forming material about a model of a patient's residual limb is well known to those skilled in the art. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

In the method of claim 10, it is the use of the defined adapter bracket in the formation of the test socket that is novel, and the specification and drawings contain ample information of various embodiments of the adapter bracket of the invention.

Accordingly, and for all of the reasons discussed above, it is requested that the Examiner reconsider and withdraw the rejection of the claims 10-19 based upon 35 USC §112, first paragraph.

### Conclusion

In view of the above discussion and amendments, all of the claims of record define patentable subject matter over the art of record. Therefore, the application is in condition for allowance, and an early Notice of Allowance is respectfully requested.

Should the Examiner wish to modify any of the language of the claims, applicant's attorney suggests a telephone interview in order to expedite the prosecution of the application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Donald A. Schurr', is written over a horizontal line.

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